K010478

SEP 2 7 2001

510(k) SUMMARY

SUBMITTER:	Dideco S.p.A. 86, Via Statale 12 Nord 41037 Mirandola (MO) Italy
CONTACT PERSON:	Luigi Vecchi Phone: 011 39 0535 29811 Fax: 011 39 0535 25229
DATE PREPARED:	February 9, 2001
DEVICE TRADE NAME:	Lilliput Phospholypidic Inert Surface In Oxygenation (Ph.I.S.I.O.) Infant/newborn Hollow Fiber Oxygenator
COMMON NAME:	Hollow Fiber Oxyenator/Reservoir
CLASSIFICATION NAMES:	Cardiopulmonary Bypass Oxygenator Cardiopulmonary Bypass Heat Exchanger Cardiopulmonary Bypass Blood Reservoir
PREDICATE DEVICE:	D901 Lilliput Ph.I.S.I.O. (K991737)

DEVICE DESCRIPTION:

The D901 Lilliput Ph.I.S.I.O is a hollow fiber membrane oxygenator with an integral heat exchanger and an attached (optional) venous reservoir. The blood contact surfaces have been coated with a phosphorylcholine coating. The coating provides a uniform biocompatible surface resulting in reduced platelet adhesion.

INDICATION FOR USE:

The Lilliput Ph.I.S.I.O is intended for use in infant/newborn patients not exceeding 17.6 lb who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation. The device provides oxygenation and removal of carbon dioxide from venous or suctioned blood. The integral heat exchanger provides blood temperature control, allows for the use of hypothermia, or aids in the maintenance of normothermia during surgery. The venous reservoir is intended to collect blood during normal operation, to assure the proper oxygenation capability of the device. The Lilliput Ph.I.S.I.O has been tested for 6 hours of continuous use; use longer than 6 hours is not advised.

TECHNOLOGICAL CHARACTERISTICS:

The Lilliput Ph.I.S.I.O hollow fiber membrane oxygenator is identical in design to the D901 Lilliput Ph.I.S.I.O hollow fiber membrane oxygenator cleared under 510(k) K991737. There are no material, technology or performance changes between the predicate and the proposed devices: the design, materials, packaging, sterilization methods, operating principles and control mechanisms are exactly the same for both products.

This 510(k) notification covers a change to the currently marketed Lilliput Ph.I.S.I.O hollow fiber membrane oxygenator. The change consists of extending the biocompatibility claims for the device to add that the phosphorylcholine coating results in reduced platelet adhesion on the treated surfaces.

IN-VITRO AND BIOCOMPATIBILITY TEST RESULTS:

A complete battery of tests was carried out in accordance with the requirements of ISO 10993-1 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing. Platelet adhesion, sterility, pyrogenicity, EO residuals, and package integrity tests were also conducted. The results of these tests met established specifications.

CONCLUSION

The results demonstrate that the phosphorylcholine coating of the Lilliput Ph.I.S.I.O effectively reduces platelet adhesion on the treated surfaces. Additional testing has also demonstrated the effectiveness of production techniques to assure that the device is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 7 2001

COBE Cardiovascular®, Inc.
c/o Ms. Lynne Leonard
Sr. Regulatory and Clinical Affairs Manager
14401 W. 65th Way
Arvada, CO 80004-3599

Re: K010478
Trade Name: Dideco D901 Lilliput Ph.I.S.I.O Hollow Fiber Membrane Oxygenator
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary bypass oxygenator.
Regulatory Class: II
Product Code: DTZ
Dated: July 16, 2001
Received: July 17, 2001

Dear Ms. Leonard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010478

Device Name: Dideco D901 Lilliput Ph.I.S.I.O Hollow Fiber Membrane Oxygenator

Indications For Use:

The Dideco D901 Lilliput Ph.I.S.I.O Infant/Newborn Hollow Fiber Membrane Oxygenator is intended for use in infants weighing not more than 8 kg (17.6 lb) who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation. It provides oxygenation and carbon dioxide removal from venous or suctioned blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The venous reservoir is intended to collect blood during normal operation, to always assure the proper oxygenation capability of the device. The Lilliput Ph.I.S.I.O should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010478

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)